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DEVICES FOR SAMPLING, DRAINAGE OR INFUSION OF LIQUIDS FROM OR TO THE HUMAN OR ANIMAL BODY ;

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ABSTRACT:

A device for use in the sampling or infusion of liquids from or to the human or animal body, comprising a chamber for receiving fluid, a cannula in communication with the chamber, at least one valve means operable in an open condition to connect the chamber with a source or drain of liquid and in a closed condition to seal the chamber therefrom, and chamber venting means allowing the escape of air from the chamber while preventing the escape of liquid therefrom.

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(54) **Improvements in or relating to devices for sampling, drainage or infusion of liquids from or to the human or animal body.**

(57) A device for use in the sampling or infusion of liquids from or to the human or animal body comprising a chamber for receiving fluid, a cannula in communication with the chamber, at least one valve means operable in an open condition to connect the chamber with a source or drain of liquid and in a closed condition to seal the chamber therefrom, and chamber venting means allowing the escape of air from the chamber whilst preventing the escape of liquid therefrom.

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IMPROVEMENTS IN OR RELATING TO DEVICES FOR SAMPLING, DRAINAGE OR INFUSION OF LIQUIDS FROM OR TO THE HUMAN OR ANIMAL BODY

This invention relates to the sampling, drainage or infusion of liquids from or to the human or animal body and in particular but not exclusively to a device for use in intravenous sampling or infusion via a cannula and to an adaptor for use in connecting the device to a catheter.

It is known for a cannula to be used in sampling or infusion of liquids in a device in which the cannula communicates with a chamber having one or more ports through which a needle or catheter may pass into the cannula. In such devices liquid may be sampled or infused by connection to a drain or a source of liquid respectively by means of a catheter. It has hitherto been a problem with such devices that an airlock may develop in the chamber or in the catheter. A further problem is that liquid may be lost during coupling of the device to catheters and the like and that under certain circumstances the loss of liquid may be hazardous for example when sampling blood from the body of an infective patient or when supplying potentially irritant medication with associated hazards to the patient and operator.

According to the present invention there is disclosed a device for use in the sampling or infusion of liquids from or to the human or animal body comprising a chamber for receiving fluid, a cannula communicating with the chamber, at least one valve means operable in an open condition to connect the chamber with a source or drain of liquid and in a closed condition to seal the chamber therefrom, and chamber venting means allowing the escape of air from the chamber whilst preventing the escape of liquid therefrom.

Preferably the venting means is a hydrophobic filter comprising an air permeable barrier of a hydrophobic material. Preferably this material is polytetrafluoroethylene having a pore size in the range 0.2 to 0.5 microns.

Advantageously the or one of the valve means may be disposed in a position and orientation permitting an elongate member such as an introducing needle or a probe catheter penetrating the valve means to extend linearly through the chamber and the cannula. An advantage of such an arrangement is that an introducing needle may be inserted through the chamber and the cannula into the body so that the cannula may then be introduced into the body or alternatively a prove catheter may be passed through the chamber and through the already introduced cannula so as to extend into the body.

Advantageously the cannula communicates with one end of the chamber, a first valve means is disposed at the other end of the chamber for admitting an elongate member and a second valve means is disposed at an intermediate position in a side port of the chamber. An advantage of such an arrangement is that a second means of injecting or sampling liquid is provided through the second valve means.

Preferably the cannula communicates with one end of the chamber whilst the venting means is disposed at or adjacent to the other end of the chamber so that in use the venting means is disposed as far away as possible from the body and releases air from the uppermost portion of the chamber. An advantage of such an arrangement is that the venting means is then optimally located for eliminating air locks.

The valve means in such a device may conveniently comprise an elastomeric membrane having a central puncture, which membrane may be penetrated at the puncture site by a co-operating ducted member to provide a flow path through the membrane in an open condition of the valve means and which is self sealing on withdrawal of the member in a closed condition of the valve means.

The term puncture here is used to indicate that the membrane has been pierced for example by a needle so that in the absence of any deforming forces the elastomeric qualities of the membrane effect a self sealing action.

Preferably such a membrane has an outer surface with respect to the chamber lying substantially flush with the surrounding outer surface of the device. Such an arrangement avoids the accumulation of matter which might serve as a bacteria trap.

Preferably the device includes means for fastening the co-operating member to the device in the open condition of the valve means so that the co-operating member is supported and secured to the device. Conveniently the fastening means is a threaded fastener which has the added advantage of providing a controlled penetrating force to the member during connection.

Preferably the membrane is of an uncured rubber material such as gumstock.

Alternatively the membrane may be of silicone rubber.

According to a further aspect of the invention there is disclosed an adaptor for use with the device comprising a co-operating ducted member having a distal end for use in penetrating the membrane at the puncture site and means for connection of a proximal end of the ducted member to a

catheter. The term catheter in this context is intended to include the tubing of a giving set or drainage set, or a syringe which may for example have a luer connector, or any other type of tube used in the sampling, drainage or infusion of liquids.

Such an adaptor is particularly advantageous where a flush fitting membrane is used in the device and where conventional catheter connectors are to be employed so that conveniently the adaptor may include a luer connector.

Advantageously the ducted member in such an adaptor is sealable at its distal end to prevent loss of liquid whilst not connected to the device and includes duct venting means allowing the escape of air from the ducted member whilst preventing the escape of liquid therefrom. This is useful when for example the adaptor is connected to an infusion prior to being connected to the device.

Preferably the adaptor includes a detachable cap having a hydrophobic filter. Conveniently the cap is threadably engageable with the adaptor.

Particular embodiments of the invention will now be described by way of example only and with reference to the accompanying drawings of which:

Figure 1 is a part sectioned elevation of a device according to the present invention having a membrane valve and showing an adaptor and a luer connector prior to assembly;

Figure 2 is a plan view of the device of Figure 1;

Figure 3 is a sectional view of the adaptor of Figure 1 having a cap in a sealing position;

Figure 4 is a similar view of the adaptor of Figure 3 and showing a cap prior to sealing;

Figure 5 shows the adaptor of Figure 3 connected with the device of Figure 1; and

Figure 6 shows an alternative device having two valve means of the silicone rubber type.

The device of Figure 1 has a chamber (1) and a cannula (2). A valve means comprising a membrane (3) is disposed opposite to and in line with the cannula (2) and has a central puncture (4). The membrane material is an uncured natural rubber and in this example is W-1028 gum having a thickness of 1/16 inch (0.159cm).

Venting means comprising a chamber filter (5) obturates a side port (6) of the chamber and comprises a polytetrafluoroethylene barrier having a pore size of 0.2 microns.

Wings (7) extend on either side of the chamber for ease of attachment of the device to a body (not shown) for example by means of adhesive tape.

An adaptor (8) includes a ducted member (9) which is tapered to facilitate penetration through the membrane (3) at the puncture site (4). The adaptor is fitted to the device by a threaded fastener comprising female threads (10) on the adaptor which engage male lugs (11) on the device so that during threaded engagement the ducted member is progressively urged through the membrane.

A catheter (12) having a female luer connector 13 may be connected to the adaptor (8) by engaging the male luer connector (14).

The adaptor (8) is provided with a detachable cap (15) as shown in Figures 3 and 4 so that in the sealing arrangement shown in Figure 3 the cap is sealed to the adaptor by a threaded connector 16. The cap (15) includes a hydrophobic cap filter (17) comprising a barrier of polytetrafluoroethylene of pore size 0.2 microns.

In Figure 5 the adaptor (8) without the cap (15) is shown connected to the device such that the ducted member (9) extends through the membrane (3) thereby creating a flow path communicating with the chamber.

Figure 6 shows an alternative device having an additional side port (18) accommodating a silicone rubber valve (19). In this embodiment the valve means (20) opposing the cannula is also of silicone rubber.

The device and the adaptor (8) as shown in Figures 1 to 5 may for example by used in connecting an intravenous infusion to a human patient by inserting the cannula into the patient and connecting the adaptor to a catheter comprising the tubing of a giving set. The cannula may be of the steel needle type in which case cannulation can by direct injection or the cannula may be of a plastics material in which case cannulation requires the use of an introducing needle which is initially inserted through the membrane (3) at the puncture site (4) so as to extend through the cannula (2) and may then be withdrawn after cannulation.

The chamber (1) serves as a flashback chamber during cannulation so that preferably the chamber is of a transparent plastics material so that the chamber may be observed to be filling with blood. During flashback air is expelled through the chamber filter (5) which prevents loss of blood by virtue of its hydrophobic properties. The pore size of the filter (5) is selected to be of the order of 0.2 microns which prevents the ingress of bacteria and the material of the filter is chosen to be non-toxic and non-reactive with the chamber contents, for example polytetrafluoroethylene.

For the purpose of volume fluid infusion, before connecting the adaptor (8) to the device it is first necessary to prime the tubing (12) of the giving set and the adaptor with the infusion liquid and this may be carried out by connecting the adaptor to the tubing using the male and female luer connectors (14 and 13) and with the cap (15) fitted to the adaptor. Liquid from the giving set is then admitted to the tubing and fills both the tubing and adaptor

completely with air being expelled through the filter (17). The use of a hydrophobic filter (17) in the cap (15) ensures that no liquid is lost during the priming operation and the use of a filter of polytetrafluoroethylene with pore size 0.2 microns ensures that the liquid is not contaminated by bacteria.

To connect the primed adaptor and tubing to the device the tubing (12) which is of a soft plastics material is clamped adjacent to the adaptor (8) and the cap (15) is then removed. No loss of liquid will occur at this stage provided the tubing (12) is adequately clamped to prevent any flow of liquid. The cap may then be discarded and is preferably is regarded as being a disposable item.

The adaptor (8) is then fitted to the device by urging the ducted member (9) through the puncture (4) of the membrane (3) and screwing the adaptor in place by means of the threaded fastener (10 and 11). The tubing may then be unclamped to release the flow of liquid and in this condition as shown in Figure 5 the flow path is established from the tubing through the adaptor and into the chamber for delivery to the patient via the cannula. The giving set may be disconnected from the patient by clamping the tubing and unscrewing the adaptor from the device to withdraw the ducted member - (9) so that the membrane (3) relaxes to its closed position as shown in Figure 1.

The setting up of a giving set for an intravenous infusion may therefore be a controlled and closed procedure using the device and adaptor of the present invention. Furthermore it is envisaged that each new giving set may be supplied with a disposable adaptor including a cap.

Additional medication may be injected to the chamber (1) where an additional port (18) is provided as shown in Figure 6.

The device and adaptor in accordance with the present invention is particularly advantageous where a patient requires self treatment involving infusion as in the case of patients suffering from haemophilia and other blood disorders. The self sealing nature of the membrane valve (3) allows the attachment of a syringe to a cannula to be a simple one hand operation. The device also has application in chemotherapy, dialysis and anaesthesia. The inclusion of the hydrophobic filter reduces the risk of air embolism or infection and enables flashback to be safely controlled without blood spillage. The device may also be used in the taking of blood samples and is particularly advantageous in obtaining samples from patients suspected of having infectious diseases where it is essential to minimise the risk of blood spillage.

Whilst membrane type valves have been shown in the preferred embodiments other types of valve may be used in the device, such as flap valves or ball valves and may be actuated either by a co-operating member or by fluid pressure.

Other arrangements are envisaged in which no adaptor is required to connect the device to a catheter for example where the valve means is incorporated in a luer connector and is actuated when engaged with a mating connector of the catheter.

A device in accordance with the present invention may be used not only for intravenous infusion and sampling but in cannulating any body cavity for infusion or drainage and may include specialised adaptations of the cannula portion of the device for such use.

It is also envisaged that a filter as disclosed above may be used in a cap attachable to the tubing of a giving set to generally avoid spillage during priming. This would avoid the present disadvantage whereby a quantity of liquid is generally lost when preparing to connect the giving set to any apparatus in order to remove air from the system. such a filter could be supplied in a disposable cap which would allow air to be vented during priming, the tubing of the giving set then being clamped and the cap discarded.

Claims

1. A device for use in the sampling or infusion of liquids from or to the human or animal body comprising a chamber (1) for receiving fluid, a cannula (2) in communication with the chamber (1), at least one valve means (3) operable in an open condition to connect the chamber (1) with a source or drain of liquid and in a closed condition to seal the chamber (1) therefrom, and chamber venting means (5) allowing the escape of air from the chamber (1) whilst preventing the escape of liquid therefrom.

2. A device as claimed in claim 1 wherein the venting means (5) is a hydrophobic filter comprising an air permeable barrier of a hydrophobic material, preferably polytetrafluoroethylene having a pore size in the range of 0.2 to 0.5 micron.

3. A device as claimed claim 1 or claim 2 wherein the or one of the valve means (3) is disposed in a position and orientation permitting an elongate member penetrating the valve means (3) to extend linearly through the chamber (1) and the cannula (2).

4. A device as claimed in claim 3 wherein the cannula (2) communicates with one end of the chamber (1), a first valve means (20) is disposed at the opposite end of the chamber for admitting an

elongate member and a second valve means (19) is disposed at an intermediate position in a side port (18) of the chamber.

5. A device as claimed in claim 3 or claim 4 wherein the cannula (2) communicates with one end of the chamber (1) and the venting means (5) is disposed at or adjacent to the opposite end of the chamber so that, in use, the venting means (5) is disposed as far away as possible from the body and so that, in use, the venting means releases air from the uppermost portion of the chamber.

6. A device as claimed in any one of the preceding claims wherein the or at least one of the valve means (3) comprises an elastomeric membrane having a central puncture (4), which membrane may be penetrated at the puncture site by a co-operating ducted member (9) to provide a flow path through the membrane in an open condition of the valve means (3) and which is self sealing on withdrawal of the member (9) in a closed condition of the valve means (3).

7. A device as claimed in claim 6 in which the outer surface of the membrane with respect to the chamber lies substantially flush with the surrounding outer surface of the device.

8. A device as claimed in claim 6 or claim 7 which includes means for fastening the co-operating member to the device in the open condition of the valve means.

9. A device as claimed in claim 7 or claim 8 wherein the membrane is made from an uncured rubber material or from silicone rubber.

10. A device as claimed in any one of the preceding claims in combination with an adaptor (8) comprising a co-operating ducted member (9) having a distal end for use in penetrating the membrane at the puncture site (4), and means for connection of a proximal end of the ducted member (9) to a catheter (12).

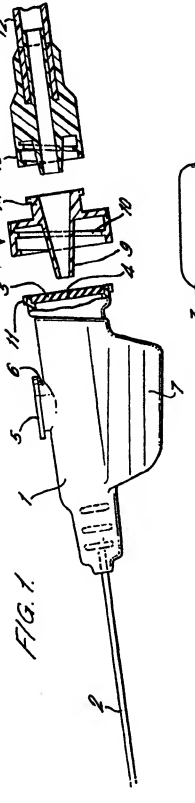

FIG. 1.

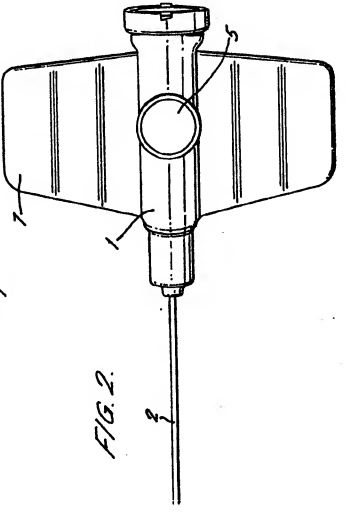

FIG. 2.

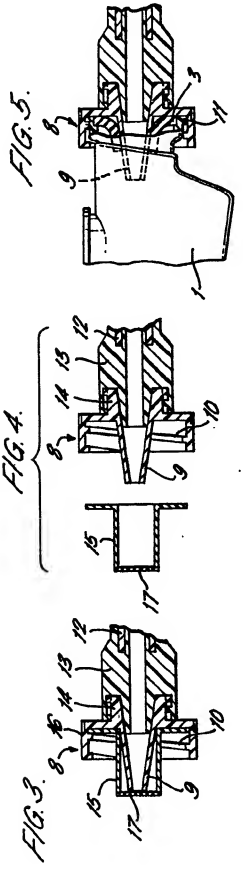
FIG. 3.
FIG. 4.
FIG. 5.
FIG. 6.
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